

REMARKS

This is in response to the Office Action that was mailed on March 12, 2003. Applicants gratefully acknowledge the intimated allowability of claims 10 and 11. Claim 10 is recast, without change of scope, in independent form. Claim 1 is amended to more particularly point out Applicants' invention. Support for the amendment is found in claim 6, in Example 5 (600°C), and in lines 34-37 on page 3 of the specification. No new matter is introduced by this Amendment. Claims 1-22 remain in the application.

The present invention provides a process for producing a composite material for dental or orthopedic use. The material comprises apatite, and contains groups that have a tendency to decompose. In accordance with the present invention, Applicants have discovered that decomposition begins to take place at elevated temperatures, as shown in the graph in Example 1 herein, at different temperatures depending on the presence or absence of a metal. Therefore a high pressure (> 100 MPa) is applied early in the process before detrimental decomposition starts and before the end temperature for the densification is reached.

None of the cited references teaches a method in which such a high pressure is applied before the end temperature is reacted. In fact, none of the cited references shows any understanding of the relationship between decomposition and the pressure-temperature parameters, or indeed any understanding of a decomposition problem at all.

Claims 1-9 and 12-22 were rejected under 35 U.S.C. §103(a) as being unpatentable over US 5,306,673 (Hermansson) or US 4,309,488 (Heide) in view of US 5,096,450 (Sugimura). The rejection is respectfully traversed.

Hermansson teach the use of HIP, but says nothing about the precise conditions of temperature in the HIP process. Applicants believe that at the time the Hermansson disclosure was formulated, nothing was known about the risk of decomposition. Applicants point out that the encasing in glass as cited by the Examiner does not mean that a pressure is applied to the capsule as required by the claims herein as amended. It is noted also that “applying of a pressure” in claim 1 as amended means a deliberate application of an external pressure, not to be confused with an increase of pressure in a closed capsule due to a rise in temperature.

Heide indicates that hot pressing and hot isostatic pressing can be used in making an implantable bone replacement body based on completely or

partially resorbable particles composed of bioactive sintered calcium phosphates. For the bone replacement body to be resorbable, tricalcium phosphate and tetracalcium phosphate are used, but **apatite is not used**. In the present invention, these phases are the decomposed phases that are **avoided** thanks to the present inventive method. Merely using hot isostatic pressing is not enough to avoid detrimental reactions. Sealing of the capsule and applying pressure to avoid decomposition and assure an early densification without losing high end product density is required to achieve a bioactive (apatite) high strength implant material. Hence, in Heide tricalcium and tetracalcium phosphate are the starting material. The reasons for this is (a) the material has already decomposed and (b) the material is resorbable. The Examiner's allegation that "It is reasonable to conclude that Heide et al would not have used pressure and temperature conditions that cause substantial decomposition of the apatite phase" lacks support or basis in the record.

Regarding Hermansson and Heide, the Examiner "submits that the references are silent in regard to the temperature that the pressure is applied [at] in the Hipping processes". This of course is an acknowledgement that the references fail to teach a pressure-temperature process in accordance with the present invention.

Sugimura does not teach anything about decomposition of biomaterials containing apatite. Instead, Sugimura deals with reactions that can take place with metal in the presence of moisture (hydroxide formation) in a metal based composite. In this case, Hot Isostatic Pressing (HIP) prevents the detrimental reactions that can occur with the metals used. The problem solved in Sugimura is however different from the present problem related to the decomposition of apatite, since the material in Sugimura **does not contain any apatite** to start with! Hence, a person of ordinary skill in the art would find no guidance in Sugimura to solve a problem related to the decomposition of apatite in a HIP process. Moreover, the pressure-temperature process in Figure 5 of Sugimura does not fulfill the requirements of the claims herein in as amended.

In Figure 5 of Sugimura, the pressure increase from 0 to 770°C is a consequence of the temperature increase in a closed system. In this case, the HIP-pressure is started to be activated at a temperature of 770°C for 15 minutes and the temperature and the pressure is then increased to the final temperature giving the final pressure at the top temperature of 1000°C. The pressure is about 20 MPa at the end of the 15 minute period at 770°C and about 100 MPa at 900°C to reach 150 MPa at the top (end) temperature.

In the present invention, a HIP pressure as high as possible (> 100 MPa) is applied early, below 900°C for ceramic based composites and at or below 600°C for metal based composites. In both cases, this is before the temperature interval where decomposition may be detrimental. An early high HIP pressure gives an early start of the densification process. The combination including avoidance of decomposition and effective densification is crucial for the apatite phase in the present invention. This is true in general, but especially in the case of a combination of oxides and apatite, where the oxides appear to catalyze an early commencement of decomposition of apatite.

It is respectfully submitted that the teachings of Hermansson and Heide, even as supplemented by the disclosure of Sugimura, fails to place those of ordinary skill in the art in possession of the invention defined by any of claims 1-22 in their present form.

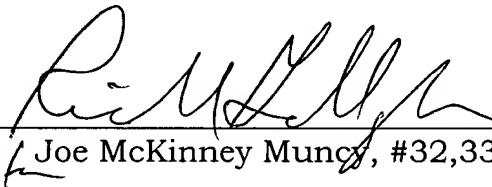
If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit

Serial No. 09/806,455
Docket No. 4013-0158P

Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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4013-0158P

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